PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 32600P WO	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/EP2005/001711	International filing date *(day/month/year)* 18 February 2005 (18.02.2005)	Priority date *(day/month/year)* 20 February 2004 (20.02.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant DEVELOGEN AKTIENGESELLSCHAFT		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 10 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 11 October 2006 (11.10.2006)
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Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2005/001711	18.02.2005	20.02.2004

International Patent Classification (IPC) or both national classification and IPC
INV. C07K14/705 A61K38/17 A61K38/55 A61K38/43 G01N33/50 A01K67/027 A61P1/18 A61P3/04 A61P3/10

Applicant
DEVELOGEN AKTIENGESELLSCHAFT FÜR ...

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2005/001711

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☒ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☒ in written format

   ☒ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☒ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2005/001711

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-40 (partially)

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 1-40 (partially) are so unclear that no meaningful opinion could be formed *(specify)*:

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 1-40 (partially)

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-40 (partially)

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-40
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-40
Industrial applicability (IA)	Yes:	Claims	1-40
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

SECTION IV

Rule 13: Unity

The international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (cf. Patent Corporation Treaty (PCT): Rule 13 and PCT International Search and Preliminary Examination Guidelines, C-II, Chapter 10).

The technical problem underlying the application is the "provision of a composition for the treatment of pancreatic disorders esp. metabolic syndrome, obesity and diabetes".

SF01-SF13 (as well as their effectors, modulators, fragments and variants cf. Incomplete Search) are proposed as a solution.

However, SF01 has already been disclosed in D1 (as well as in D2 - D4) for the treatment of pancreatic disorders esp. metabolic syndrome, obesity and diabetes. Therefore, the therapeutic use is known and cannot serve as the linking single inventive concept.

In the present application, no further technical feature can be identified which could be regarded as "special technical feature" linking the different solutions (SF01-SF13).

Consequently, the application lacks unity of invention a posteriori, and the different solutions not belonging to a common inventive concept are identified as different inventions. Each of the defined inventions is characterized by its own special technical feature, defining the contribution which each of the claimed inventions makes over the prior art:

Invention 1: claims 1-40 partially, concerning SF01 relating to TNF-related molecules.

Invention 2: claims 1-40 partially, concerning SF02 relating to a developmentally regulated vital protein.

Invention 3: claims 1-40 partially, concerning SF03, a member of the glypican family.

Invention 4: claims 1-40 partially, concerning SF04 relating to precursors for alpha-microglobulin and bikunin.

Invention 5: claims 1-40 partially, concerning SF05, a neural-specific serine protease inhibitor.

Invention 6: claims 1-40 partially, concerning SF06, secreted by the brain and involved in the regulation of steroid hormone secretion.

Invention 7: claims 1-40 partially, concerning SF07, a putative tumour suppressor gene.

Invention 8: claims 1-40 partially, concerning SF08, a carboxypeptidase.

Invention 9: claims 1-40 partially, concern SF09, a 145 aa polypeptide containing calcium ion binding EF-hand motifs.

Invention 10: claims 1-40 partially, concerning SF10 relating to an extracellular integrin-binding matrix protein.

Invention 11: claims 1-40 partially, concerning SF11, a cysteine-proteinase inhibitor for cathepsins B and L.

Invention 12: claims 1-40 partially, concerning SF12, an extracellular matrix and plasma glycoprotein.

Invention 13: claims 1-40 partially, concern SF13, a proinflammatory factor for T-lymphocytes.

Only the first invention was searched, therefore, only Invention 1 has been examined.

SECTION V

Subject matter

Independent claim 1 claims a pharmaceutical composition comprising SF01 protein or nucleic acid and/**or** a functional *fragment* and/**or** an *effector/modulator (cf. also Section VIII, Article 6).*

Independant claims 13 and 14/23/35/36/37/38 relate to the first/further medical use of the composition in claims 1/8/27.

Independant claims 24/29 relate to the use of/method of using SF01 in the identification

of "*substances/*(poly)peptides *interacting with SF01*", claims 30/31 to the screening for "*agents which effect/modulate the interaction of a SF01 with a binding target*" and claims 25 and 27 to a non-human transgenic animal and a recombinant host cell exhibiting a modified expression of the SF01.
Claims 32, 34 relate to the pharmaceutical production/use of the *agent* identified in claim 29 *(cf. also Section VIII, Article 6).*
Claim 39 relates to the use of SF01 for the production of a non-human transgenic animal.
Claim 40 relates to a kit comprising SF01 nucleic acid or an functional fragment (a) **or** (b)-(h).

Novelty

Pharmaceutical compositions comprising SF01 have already been disclosed in D1-D4 as well as their use in the treatment of diabetes, obesity etc.
Also host cells, transgenic animals, screening methods, kits etc. have already been disclosed in these documents (for details cf. passages cited in the International Search Report).
Therefore, the claims are not novel.

SECTION VII and VIII
Article 5 and 6

The italic terms used in claim 1, 4, 23, 24 etc. "...**or** a functional *fragment* and/**or** an *effector/modulator ... fragment* or *variant*" are ambiguous and render the claims unclear. The attempted characterization in some dependant claims recites only the underlying technical problem, in other words the result to be achieved for example in dependant claim 6 "wherein said nucleic acid encodes a polypeptide contributing to regulating the metabolism".

The above applies even more to independant claims 32 and 34 claiming the use of "*agents*" to be identified by methods as claimed before. The "*agents*" in these "reach-through" claims are unclear and not sufficiently disclosed in the application.
In other words it is not clear which structural features would be required to achieve the required functional features. Therefore, the skilled person would not know which compounds are covered by he scope of the claim, without undue burden and inventive skill. Furthermore, the person skilled in the art would not be able to carry out the

invention over its entire scope because instructions on how to obtain compounds with the structural features necessary to fulfill the functional definitions used in the claims are not provided in the application.
Therefore, the above articles are not fulfilled.